(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
12 September 2003 (12.09.2003)

PCT

(10) International Publication Number
WO 03/073963 A2

(51) International Patent Classification[7]: A61F 2/06

(21) International Application Number: PCT/US03/04359

(22) International Filing Date: 14 February 2003 (14.02.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/087,127 28 February 2002 (28.02.2002) US

(71) Applicant *(for all designated States except US)*: **COUNTER CLOCKWISE, INC.** [US/US]; 2030 46th Avenue, San Francisco, CA 94116 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **HEBERT, Stephen** [US/US]; 2801 College Avenue, Apt. 3, Berkeley, CA 94705 (US). **LEVINE, Marc-Alan** [US/US]; 2030 46th Avenue, San Francisco, CA 94116 (US).

(74) Agents: **HAN, Johney, U.** et al.; Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, CA 94304-1018 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 03/073963 A2

(54) Title: GUIDEWIRE LOADED STENT FOR DELIVERY THROUGH A CATHETER

(57) Abstract: A guidewire loaded stent for delivery through a catheter is described herein. The stent delivery assembly can deliver and place a stent within tortuous regions of the body which are accessible to guidewires but inaccessible to stenting catheters. The assembly comprises a guidewire covered in part by a ratractable sheath and a radially expandable stent near or at the distal end of the guidewire. The whole assembly is advanced through conventional catheters or it may be used alone. In either case, when the stent is adjacent to a treatment site within the body, the sheath is retracted proximally to expose the stent for radial expansion into contact with the vessel wall. Radio-opaque marker bands are optionally located on either side or both sides of the stent on the guidewire body to aid in visual placement. The assembly can optionally include an expandable balloon on the guidewire for different treatment modalities.

GUIDEWIRE LOADED STENT FOR DELIVERY THROUGH A CATHETER

TECHNICAL FIELD OF THE INVENTION

The present invention relates generally to catheters and intravascular medical procedures. More particularly, it relates to methods and apparatus for delivering a stent through a catheter by way of a guidewire delivery device.

BACKGROUND ART OF THE INVENTION

Intravascular stents are well known in the medical arts for the treatment of vascular stenoses. Stents are prostheses which are generally tubular and which expand radially in a vessel or lumen to maintain its patency. For deployment within the body's vascular system, most stents are mounted onto a balloon angioplasty catheter for deployment by balloon expansion at the site of a dilated stenosis or an aneurysm. Self-expanding stents, which typically expand from a compressed delivery position to its original diameter when released from the delivery device, generally exert a radial force on the constricted portion of the body lumen to re-establish patency. One common self-expanding stent is manufactured of Nitinol, a nickel-titanium shape memory alloy, which can be formed and annealed, deformed at a low temperature, and recalled to its original shape with heating, such as when deployed at body temperature in the body.

To position a stent across an area of stenosis or an aneurysm, a guiding catheter having a preformed distal tip is percutaneously introduced into the vascular system of a patient by way of, e.g., a conventional Seldinger technique, and advanced within the vasculature until the distal tip of the guiding catheter is seated in the ostium of a desired artery. A guidewire is then positioned within an inner lumen of a dilatation catheter and then both are advanced through the guiding catheter to the distal end thereof. The guidewire must first be advanced out of the distal end of the guiding catheter into the patient's coronary vasculature until the distal end of the guidewire crosses a lesion to be dilated, then the catheter having a stent positioned on the distal portion is advanced into the patient's vasculature over the previously introduced guidewire until the stent is properly positioned across the lesion. Once in position, the stent may be released accordingly.

It is generally desirable to have catheters which present small cross sectional diameters to enable access into small sized vessels. However, conventional techniques and apparatus typically require the use of a guidewire for the desirable placement of the

catheter and stent within the vasculature. Thus, conventional catheters typically require a separate lumen within the catheter body to allow for the passage of a guidewire therethrough. This separate lumen necessarily adds to the cross sectional profile of the device. Yet vasculature having a tortuous path and/or a small diameter, such as the intracranial vasculature, present problems for the conventional stenting catheter. Accordingly, a highly flexible stenting apparatus which is capable of accessing tortuous regions and which presents a small cross section is needed.

SUMMARY OF THE INVENTION

A highly flexible stent delivery assembly is described below. The assembly has the desirable characteristics of guidewires in traversing tortuous vasculature, including small cross sectioned vessels. The stent delivery assembly of the present invention is thus able to deliver and place a stent anywhere in the vasculature or within the body that is readily accessible by a guidewire but is not normally accessible by a stenting catheter body which would ride over such a guidewire.

The stent delivery assembly may typically comprise a guidewire body which is preferably covered at least in part by a retractable sheath. A radially expandable stent is disposed directly in contact about the guidewire preferably near or at the distal end of the guidewire. The retractable sheath preferably covers the entire stent during deployment and placement, and is retractable proximally to uncover or expose the stent for radial expansion. A pair of optionally placed radio-opaque marker bands may be located on either side (distally or proximally) or both sides of the stent on the guidewire body.

The sheath may have a flush port, which is in fluid communication with the distal end of the assembly, located near the proximal end of the sheath. The flush port enables a fluid, e.g., saline, to be passed through the assembly prior to insertion into the vasculature for flushing out air or debris trapped between the sheath and guidewire. It may also be used to deliver drugs or fluids within the vasculature as desired.

Because the guidewire body, rather than a catheter body, carries and delivers the stent through the vasculature, the stent may be placed almost anywhere in the body accessible by a conventional guidewire. This may include, e.g., the tortuous intracranial vasculature as well as, e.g., the more accessible coronary vasculature. Furthermore, the assembly, which may include the guidewire, sheath, and stent, may be introduced into a wide variety of conventional catheters. This portability allows for flexibility in using the

same type of assembly in an array of conventional catheters depending upon the desired application and the region of the body to be accessed.

The sheath may be made from various thermoplastics, e.g., PTFE, FEP, Tecoflex, etc., which may optionally be lined on the inner surface of the sheath or on the outer surface of the guidewire or on both with a hydrophilic material such as Tecoflex or some other plastic coating. Additionally, either surface may be coated with various combinations of different materials, depending upon the desired results. It is also preferably made to have a wall thickness of about, e.g., 0.001 in., thick and may have an outer diameter ranging from about 0.0145 to 0.016 in. or greater. The sheath may be simply placed over the guidewire and stent, or it may be heatshrinked to conform closely to the assembly.

The guidewire body may be made of a conventional guidewire or it may also be formed from a hypotube having an initial diameter ranging from 0.007 to 0.014 in. Possible materials may include superelastic metals and alloys, e.g., Nitinol, or metals such as stainless steel, or non-metallic materials, e.g., polyimide. The hypotube may be further melted or ground down, depending upon the type of material used, into several sections of differing diameters. The distal end of the guidewire may be further tapered and is preferably rounded to aid in advancement through the vasculature. Radio-opaque coils may be placed over a portion of distal end to aid in radiographic visualization.

The stent may be configured to be self expanding from a constrained first configuration when placed upon guidewire to a larger expanded second configuration when deployed. When the sheath is retracted proximally, the stent preferably self expands to a preconfigured diameter of, e.g., about 0.060 in. (1.5 mm), and up to a diameter of about 0.315 in. (8 mm). Various materials may be used to construct the stent such as platinum, Nitinol, other shape memory alloys, or other self expanding materials.

Other variations may include a guidewire which defines a stepped section near the distal end of the guidewire. The stepped section outer diameter is less than the uniform diameter defined by the remainder of the guidewire. The stent may be placed over this section while maintaining a flush outer diameter which may facilitate delivery of the stent-guidewire assembly not only through catheter body but within the vasculature. The guidewire may be further formed into tapered section distally of the stepped section.

When in use in tortuous pathways, such as intracranial vessels, the guidewire assembly may be used with the sheath alone or in combination with a delivery catheter. The catheter body may be advanced within the vessel to a treatment location such as an

aneurysm. Once the catheter is near the treatment site, the guidewire may be advanced out of the catheter and adjacent the treatment site. The sheath may then be retracted proximally to expose the stent to radially expand into contact with the walls of the vessel. Alternatively, the sheath may be held stationary while the guidewire and stent are advanced to expose the stent, e.g., as when deploying a coil stent. The stent may be self expanding or configured to expand upon the application of an electric current with or without the sheath. In either case, once the stent has been released from the guidewire and expanded, both the guidewire and sheath may be withdrawn into the catheter body and removed from the vicinity. The catheter may be left within the vessel to allow for the insertion of additional tools or the application of drugs near the treatment site.

Other variations may include an expandable balloon section preferably located distally of the stent. In this case, treatment preferably includes the expansion of the balloon first to mitigate any occlusions within the vessel. The stent may then be released in a manner similar to that described above. Once the balloon has been deflated and the stent expanded, the assembly may be removed from the vicinity.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1A shows a variation on the stent delivery assembly where a guidewire has a stent disposed on the wire near its distal end.

Fig. 1B shows another variation on the assembly where the guidewire may have an expandable balloon located near the distal end of the wire.

Fig. 2 shows a representative illustration of the guidewire and stent assembly which is insertable within a catheter; the assembly shows the guidewire surrounded by a partially retracted sheath which exposes the stent.

Fig. 3 shows a cross sectioned side view of a variation of the stent delivery assembly placed within a catheter body lumen.

Fig. 4 shows a cross sectioned side view of another variation of the stent delivery assembly also placed within a catheter body lumen.

Fig. 5 shows a cross sectioned side view of yet another variation of the stent delivery assembly having an expandable balloon section.

Figs. 6A to 6C illustrate an example of one method of placing a stent within a hollow body organ using the guidewire assembly.

Figs. 7A to 7C illustrate an example of another method of placing a stent within the hollow body organ in combination with an expandable balloon.

DETAILED DESCRIPTION OF THE INVENTION

A stent delivery assembly having a small cross section and which is highly flexible is described herein. As shown in Fig. 1A, catheter assembly **10** is comprised of a conventional catheter body **12** having a distal end **14** and a proximal end **16**. A fitting assembly **18** is attached to the proximal end **16** and may preferably have various attachments, e.g., Luer lock **20**, to allow for access to catheter body **12** or the use of other instruments. Conventional catheter body **12** shows guidewire assembly **22** being slidably positioned therewithin. Assembly **22**, which is described in further detail below, is shown in this variation as having a guidewire body **24** preferably covered at least in part by a retractable sheath **26**. A radially expandable stent **28** is preferably disposed near the distal end of guidewire **24**. Stent **28** may also be placed between an optional pair of radio-opaque marker bands **30, 32**. One or both marker bands **30, 32** may be used or they may be left off the assembly entirely. The use of radio-opaque material allows for the visualization of the assembly during placement within the vasculature. Such visualization techniques may include conventional methods such as fluoroscopy, radiography, ultrasonography, magnetic resonance imaging, etc.

Fig. 1B shows the distal portion of catheter body **12** with another guidewire variation **34** which has an optional angioplasty balloon **36**. As shown in this variation, balloon **36** is preferably located distally of stent **28** and may be sufficiently deflated such that sheath **26** may be placed over both stent **28** and balloon **36**.

Fig. 2 shows a representative illustration of the stent delivery assembly **40** removed entirely from the delivery catheter body with guidewire **24** covered by sheath **26**. Stent **28** is preferably placed directly over guidewire body **24** and is covered by sheath **26**. Sheath **26** may have a flush port **42** located near the proximal end of the sheath **26**. Flush port **42** is preferably in fluid communication with the distal end of the assembly **40** so that a fluid, e.g., saline, may be passed through the assembly **40** prior to insertion into the vasculature for flushing out air or debris trapped between the sheath **26** and guidewire **24**. Flush port **42** may also be used to deliver drugs or fluids within the vasculature as desired.

Because the guidewire body **24**, rather than a catheter body, carries and delivers stent **28** through the vasculature, the stent **28** may be placed almost anywhere in the body

by a conventional guidewire. This may include, e.g., the tortuous intracranial vasculature as well as, e.g., the more accessible coronary vasculature. Furthermore, assembly **40**, which may include the guidewire **24**, sheath **26**, and stent **28**, may be introduced into a wide variety of conventional catheters. This portability of assembly **40** allows for flexibility in using the same type of assembly **40** in an array of conventional catheters depending upon the desired application and the region of the body to be accessed.

The sheath **26** may be made from various thermoplastics, e.g., PTFE, FEP, Tecoflex, etc., which may optionally be lined on the inner surface of the sheath or on the outer surface of the guidewire or on both with a hydrophilic material such as Tecoflex or some other plastic coating. Additionally, either surface may be coated with various combinations of different materials, depending upon the desired results. Sheath **26** is preferably made to have a wall thickness of about 0.001 in. thick, and optionally thicker, and may have an outer diameter ranging from about 0.0145 to 0.016 in., or greater. Sheath **26** may also be placed over guidewire body **24** having a diameter of about 0.038 in. When placed over guidewire body **24** and stent **28**, it may be simply placed over to slide along wire **24** or it may also be heatshrinked over the wire **24** and stent **28** to conform closely to the assembly.

A more detailed view of the guidewire assembly is shown in the cross sectioned side view in Fig. 3. As seen, the distal end of guidewire body **24** is shown loaded within sheath lumen **60** of sheath **26** and this assembly is shown as being disposed within catheter lumen **62** of catheter body **12**. As previously discussed, because stent **28** is placed upon a guidewire body rather than a catheter body, the assembly may be introduced into any part of the body which is accessible by a conventional guidewire but which is not normally accessible for stenting treatments.

The guidewire body **24** may be made of a conventional guidewire and it may also be formed from a hypotube having an initial diameter ranging from 0.007 to 0.014 in. The hypotube or guidewire may be made from a variety of materials such as superelastic metals, e.g., Nitinol, or it may be made from metals such as stainless steel. During manufacture, a proximal uniform section **50** of the hypotube may be made to have a length of between about 39 to 87 in. (100 to 220 cm), preferably between about 63 to 71 in. (160 to 180 cm), having the initial diameter of 0.007 to 0.022 in., preferably 0.008 in. The hypotube may be further melted or ground down into a tapered section **52**, depending upon the type of material used, which is distal to the proximal uniform section **50**. Tapered

section **52** may have a length of about 4 in. (10 cm) to reduce the diameter down to about 0.002 to 0.003 in. The hypotube may be further formed to have a distal uniform section **54** of about 2 in. (5 cm) in length over which the stent **28** is preferably placed. Radio-opaque marker bands may optionally be placed either distally **30** or proximally **32** of stent **28** to visually aid in the placement of the stent **28**, as is well known in the art. Alternatively, distal and proximal marker bands **30**, **32** may be eliminated altogether. Marker bands **30**, **32** may be used as blocks or stops for maintaining the stent in its position along guidewire body **24**. Alternatively, if bands **30**, **32** are omitted from the device, stops or blocks may be formed integrally into the guidewire body **24** or they may be separately formed from material similar to that of guidewire body **24** and attached thereto.

Distal end **56** may be further tapered beyond distal uniform section **54** to end in distal tip **58**, which is preferably rounded to aid in guidewire **24** advancement. A coil, preferably made from a radio-opaque material such as platinum, may be placed over a portion of distal end **56**. Alternatively, a radio-opaque material, e.g., doped plastics such as bismuth or tungsten, may be melted down or placed over a portion of distal end **56** to aid in visualization. Stent **28** is preferably made to be self expanding from a constrained first configuration, as when placed upon guidewire **24** for delivery, to a larger expanded second configuration as when deployed within the vasculature. Stent **28** may be constrained by sheath **26** to a diameter of, e.g., 0.014 in., while being delivered to a treatment site within the body, but when sheath **26** is retracted proximally, stent **28** preferably self expands to a preconfigured diameter of, e.g., about 0.060 in. (1.5 mm), and up to a diameter of about 0.315 in. (8 mm). Various materials may be used to construct stent **28** such as platinum, Nitinol, other shape memory alloys, or other self expanding materials. Sheath **26** may also have drainage ports or purge holes **64** formed into the wall near the area covering stent **28**. There may be a single hole or multiple holes, e.g., three holes, formed into sheath **26**. Purge holes **64** allow for fluids, e.g., saline, to readily escape from inbetween sheath **26** and guidewire **24** when purging the instrument, e.g., to remove trapped air or debris.

Fig. 4 shows a cross sectioned side view of another variation **70** of the stent delivery assembly. As shown, guidewire variation **70** is shown as being surrounded by sheath **26** and the sheath-guidewire assembly is shown as being placed within catheter lumen **62** prior to delivery of the stent. In this variation, the guidewire may have a uniform section **72** like that described in Fig. 3 above. However, there is also a stepped section **74** defined in the guidewire outer diameter near the distal end of the guidewire. Within this section **74**, the

stepped outer diameter is less than the uniform diameter defined by the guidewire uniform section **72**. It is over this stepped section **74** that stent **84** may be placed along with optional distal and/or proximal marker bands **80**, **82**, respectively, such that sheath **26** remains flush over this section. Maintaining a flush outer diameter may facilitate delivery of the stent-guidewire assembly not only through catheter body **12** but within the vasculature. The guidewire may be further formed into tapered section **76** distally of stepped section **74**. And the guidewire may be finally formed into a distal tip **78** over which coil **86** may be optionally placed. Coil **86** may optionally be covered by a covering **88**, e.g., a polymer or other plastic material, placed or heatshrinked over the coil **86** and distal tip **78** to provide a smooth section.

Fig. 5 shows a cross sectioned side view of yet another variation of the stent delivery assembly having an expandable balloon section. As shown, much of the guidewire is similar to variations described above but with the addition of an expandable balloon **36** which may be inflated to an expanded balloon **36'**. The variation shown may have a uniform section **90** which similarly tapers down **92** into a distal uniform section **94**, over which stent **28** may be placed. Although balloon **36** may be placed proximally of stent **94**, it is preferably located distally of stent **94**, as shown. When deflated, retractable sheath **26** may also be placed over balloon **36** to provide a uniform profile. To accommodate the inflation and deflation of balloon **36**, a small inflation lumen (not shown) may be defined within the body of the guidewire for the passage of fluids into and out of the balloon **36**. A coil may also be optionally placed over distal end **96**; alternatively, a radio-opaque material may be melted down or placed over distal end **96**.

In operation, the stent delivery guidewire may be used with or without the catheter body to deliver the assembly intravascularly. It is preferable that a catheter be used to provide a pathway close to the treatment site. However, in tortuous pathways, such as intracranial vessels, the guidewire device may be used with the sheath alone if the catheter body presents too large a cross section for delivery purposes. Figs. 6A to 6C show an example of the deployment of the guidewire assembly. Catheter body **12** may first be advanced within the lumen **102** of vessel **100** to a treatment location, e.g., aneurysm **104**. Once catheter body **12** has reached a position near aneurysm **104**, guidewire **24** may be advanced through and out of catheter **12** with sheath **26** covering stent **28**, as seen in Fig. 6A. As guidewire **24** is advanced, stent **28** located on guidewire **24** may be positioned via radio-opaque marker bands **30**, **32** to the desired location, such as over the neck **106** of

aneurysm **104**. Once guidewire **24** and stent **28** have been properly positioned, sheath **26** may be retracted proximally to expose stent **28** to the vascular environment, as shown in Fig. 6B.

Stent **28**, as shown in Fig. 6C, may be left to radially self expand into gentle contact with the walls of vessel **100** to occlude the neck **106** of aneurysm **104** (as is well known in the art). Stent **28** may also be configured to expand upon the application of an electric current actuated from a location external of the patient. The current may be delivered to stent **28** via an electrical connection or line (not shown) disposed within the body of guidewire **24**. Once the stent **28** has been released from the guidewire body **24** and expanded into contact with vessel **100**, guidewire **24** and sheath **26** may be withdrawn into catheter body **12** and removed entirely from catheter **12** or the catheter **12** itself may then be removed entirely from the body of the patient. If guidewire **24** and sheath **26** are removed only, catheter **12** may be left in position within vessel **100** to allow for the insertion of additional tools or the application of drugs near the treatment site.

Treatment may also be accomplished with the guidewire variation having an expandable balloon section. Fig. 7A shows vessel **110** which is stenosed with an obstruction **112**. Once catheter body **12** has been positioned within vessel **110**, guidewire body **34** may be advanced out of catheter **12** while still covered by sheath **26**. Balloon **36** may then be positioned adjacent to the obstruction **112** optionally guided by marker bands **30**, **32**. Once positioned, balloon **36** may be expanded to balloon **36'**, as shown in Fig. 7B, to open the stenosed vessel. After the obstruction **112** has been opened, balloon **36** may be deflated and the guidewire body **34** may be advanced distally to position sheath **28** adjacent to obstruction **112**. Sheath **26** may then be retracted to expose stent **28** to expand, as described above, into contact against obstruction **112** and vessel **110**. Fig. 7C shows the placement of guidewire **34** and expanding stent **28** over obstruction **112**.

The applications of the guidewire assembly and methods of use discussed above are not limited to the deployment and use within the vascular system but may include any number of further treatment applications. Other treatment sites may include areas or regions of the body such as organ bodies. Modification of the above-described assemblies and methods for carrying out the invention, and variations of aspects of the invention that are obvious to those of skill in the art are intended to be within the scope of the claims.

CLAIMS

What is claimed is:

1. A stent delivery assembly comprising:

an elongate wire having a proximal end, a distal end, and a length therebetween;

a radially expandable stent positioned coaxially on the wire towards the distal end; and

a tubular sheath member covering at least a portion of the wire wherein the sheath is retractable from a first position where the stent is covered by the sheath to a second position where the stent is uncovered,

wherein the assembly is adapted for insertion within a catheter body lumen.

2. The assembly of claim 1 further comprising a coil disposed at the distal end of the wire.

3. The assembly of claim 2 wherein the coil is radio-opaque.

4. The assembly of claim 1 wherein the wire comprises a tapered section located proximally of the stent.

5. The assembly of claim 1 wherein the wire comprises a tapered section located distally of the stent.

6. The assembly of claim 1 wherein the wire has a first diameter and at least one section having a second diameter which is smaller than the first diameter and wherein the stent is positioned coaxially about the second diameter.

7. The assembly of claim 1 further comprising at least one radio-opaque marker band located on the wire proximally or distally of the stent.

8. The assembly of claim 1 wherein the radially expandable stent is comprised of a radio-opaque material.

9. The assembly of claim 8 wherein the radio-opaque material comprises platinum.

10. The assembly of claim 1 wherein the radially expandable stent is comprised of a shape memory alloy.

11. The assembly of claim 10 wherein the shape memory alloy comprises Nitinol.

12. The assembly of claim 1 wherein the sheath further comprises a flush port located near a proximal end of the sheath, wherein the flush port is in fluid communication with a distal end of the sheath.

13. The assembly of claim 1 further comprising an inflatable angioplasty balloon section located near the distal end of the wire.

14. The assembly of claim 13 wherein the balloon section is located proximally or distally of the stent.

15. A method of delivering a stent within a hollow body organ comprising:
advancing an elongate wire having a proximal end, a distal end, and a length therebetween through a catheter body lumen to a preselected treatment site within the hollow body organ, wherein at least a portion of the wire is covered by a tubular sheath member;
positioning a radially expandable stent adjacent to the treatment site, wherein the stent is positioned coaxially towards the distal end of the wire; and
retracting the sheath member distally along the wire such that the stent expands radially into contact over the treatment site.

16. The method of claim 15 further comprising positioning a radially expandable balloon section adjacent to the treatment site prior to positioning the radially expandable stent, wherein the balloon section is the located near the distal end of the wire.

17. The method of claim 16 further comprising expanding the balloon section against the treatment site.

18. The method of claim 15 further comprising flushing a fluid between the wire and the tubular sheath member prior to advancing the elongate wire through the catheter body lumen.

19. The method of claim 15 wherein positioning the radially expandable stent adjacent to the treatment site comprises determining the stent location relative to the treatment site via at least one radio-opaque marker located on the wire.

20. The method of claim 15 wherein retracting the sheath member distally comprises moving the sheath member relative to the wire from a first position where the stent is covered by the sheath to a second position where the stent is uncovered.

21. The method of claim 15 further comprising advancing the catheter body through the hollow body organ to the treatment site prior to advancing the elongate wire.

22. The method of claim 15 further comprising withdrawing the wire from the catheter body lumen.

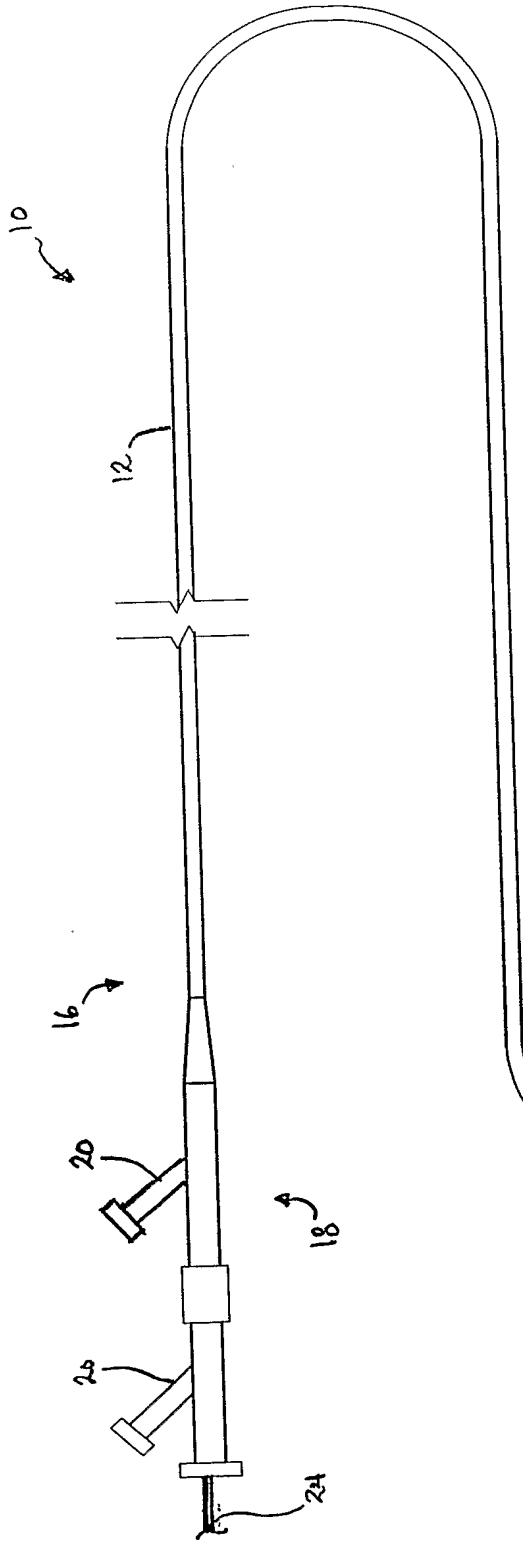

FIG. 1A

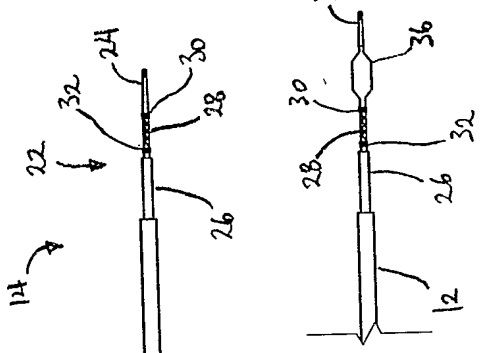

FIG. 1B

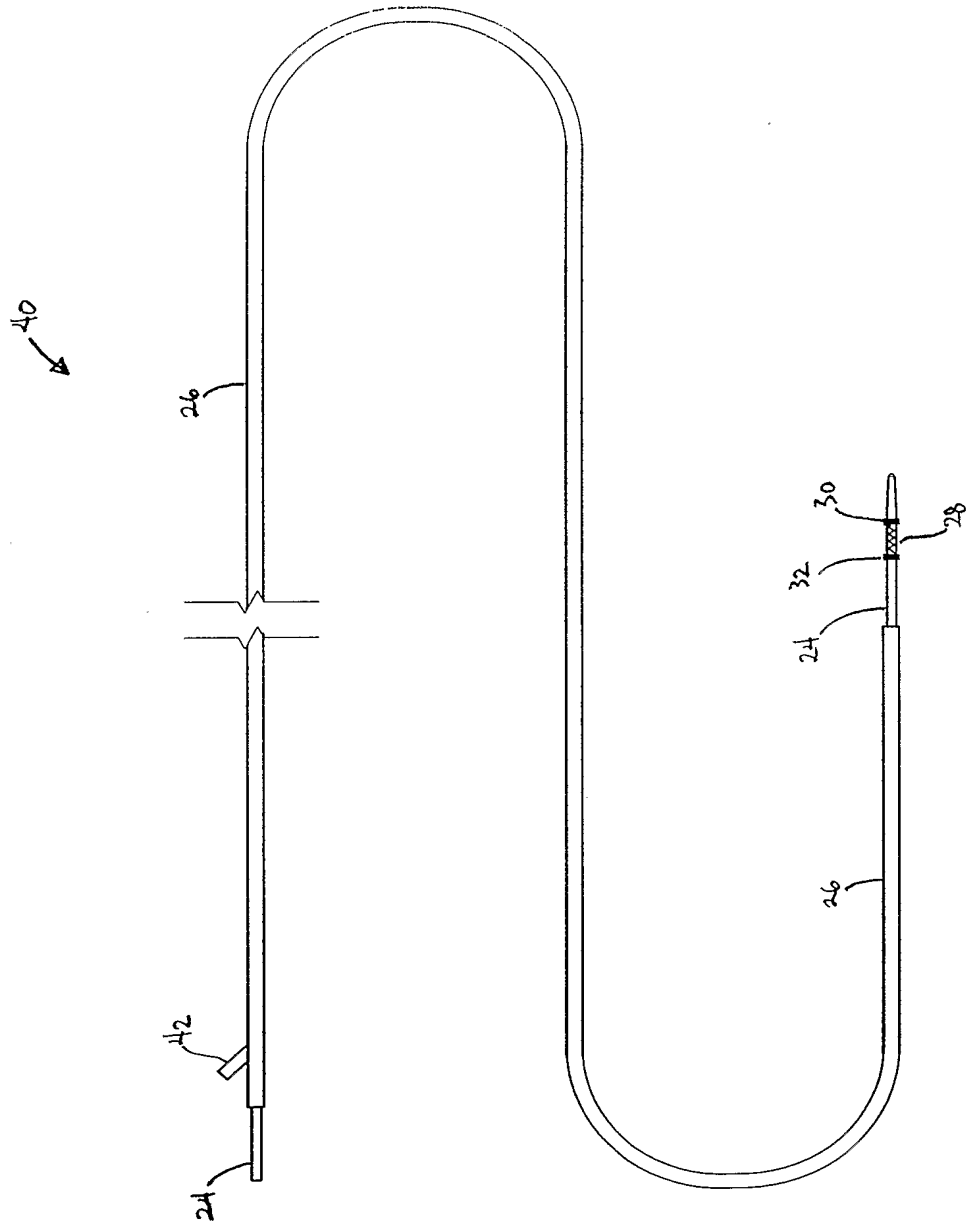

FIG. 2

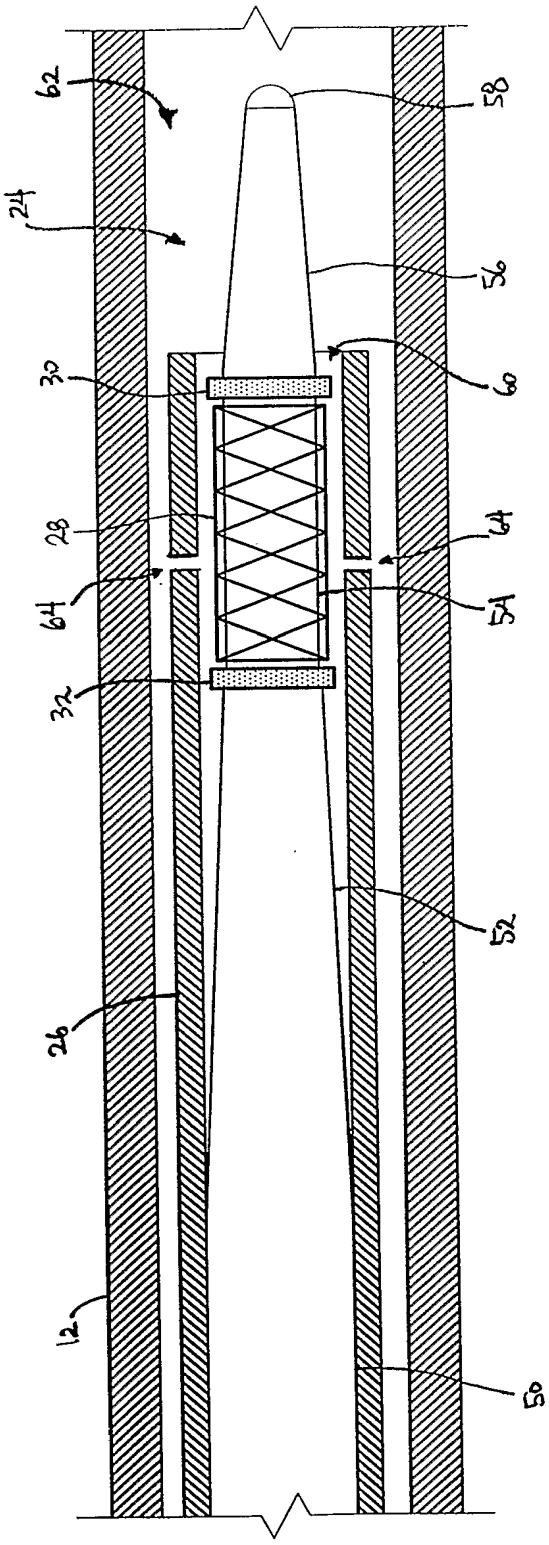
62
58
24
56
30
60
28
64
64
54
32
52
26
12
50

FIG. 3

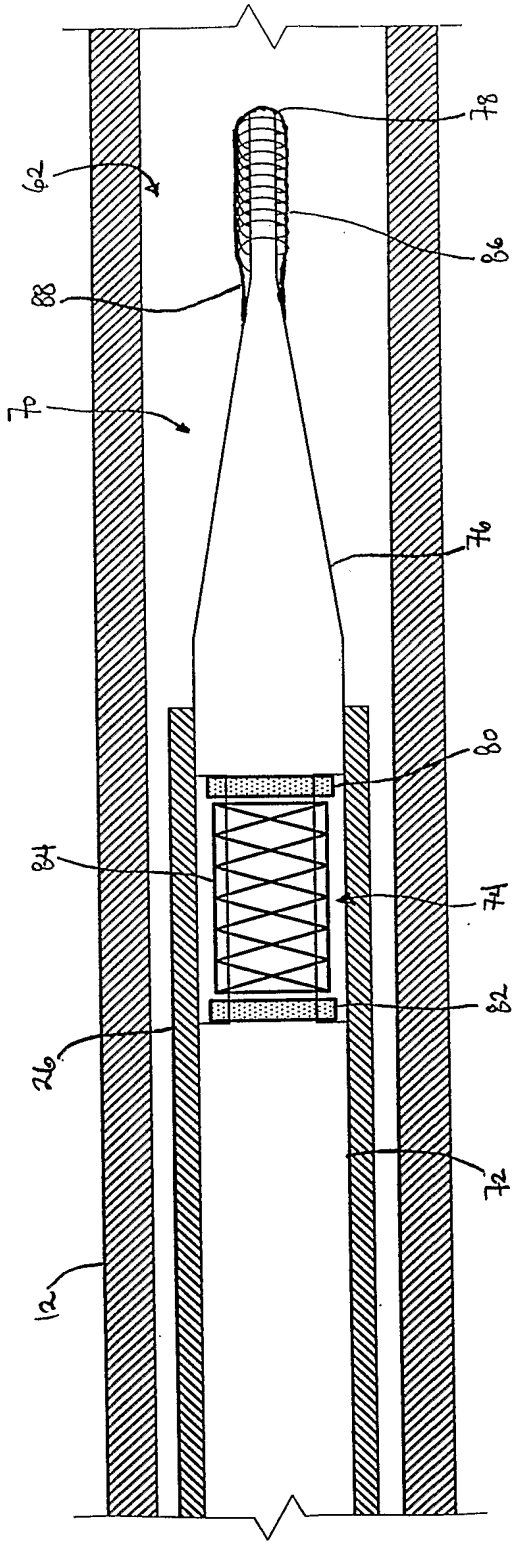
78
62
86
88
70
76
80
84
74
82
26
72
12

FIG. 4

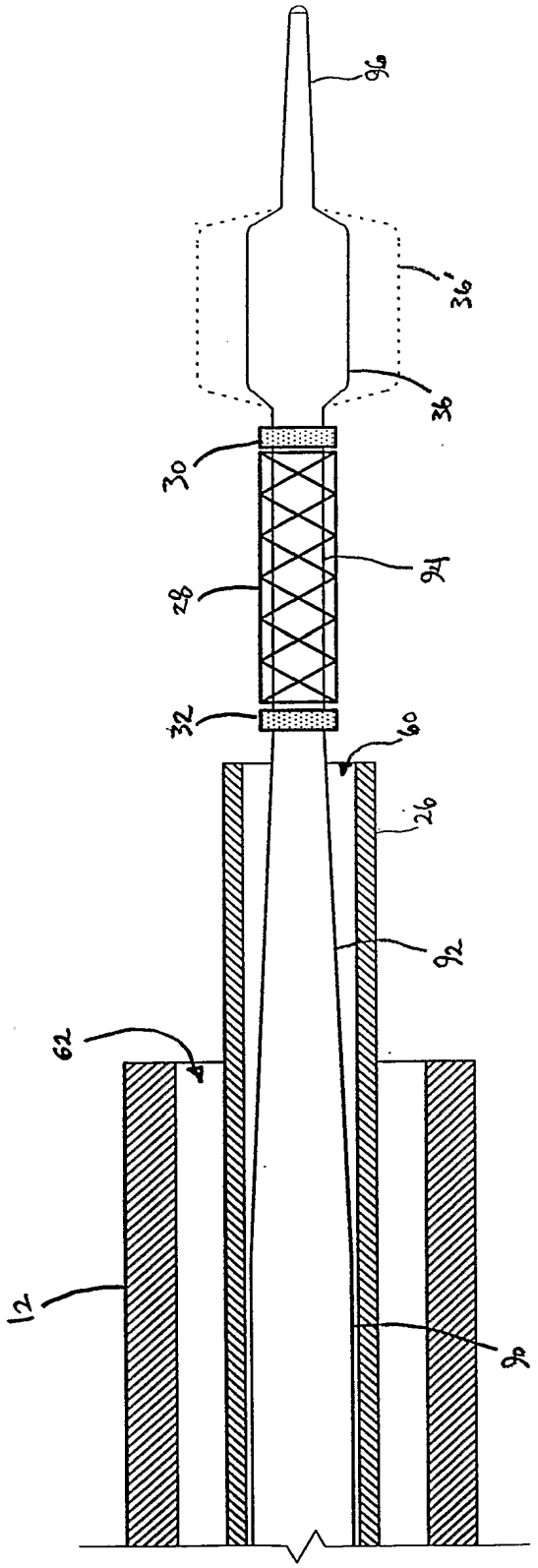

FIG. 5

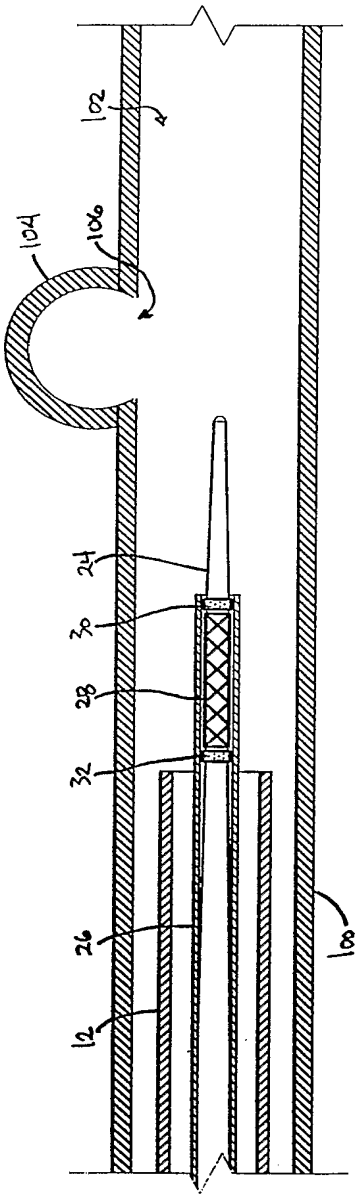

FIG. 6A

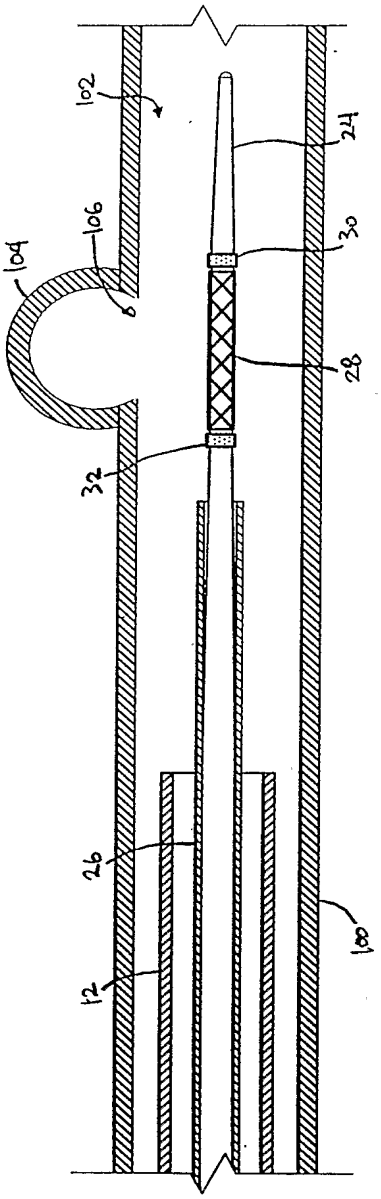

FIG. 6B

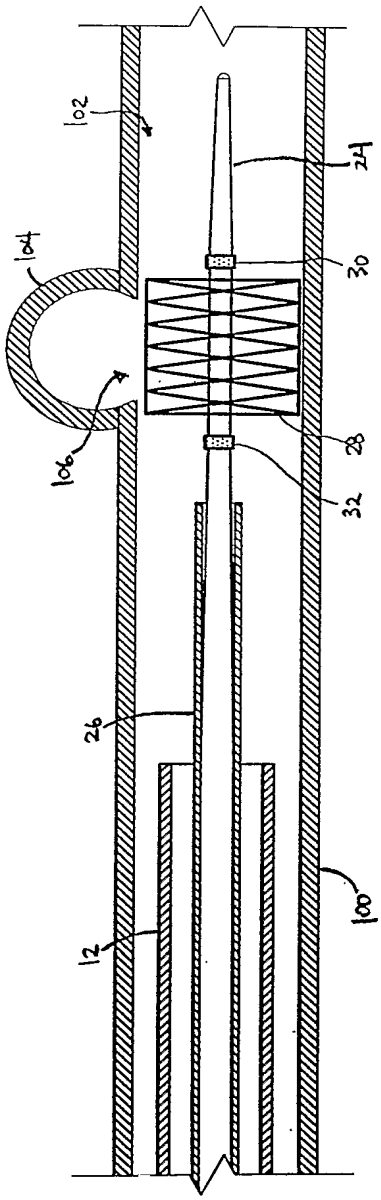

FIG. 6C

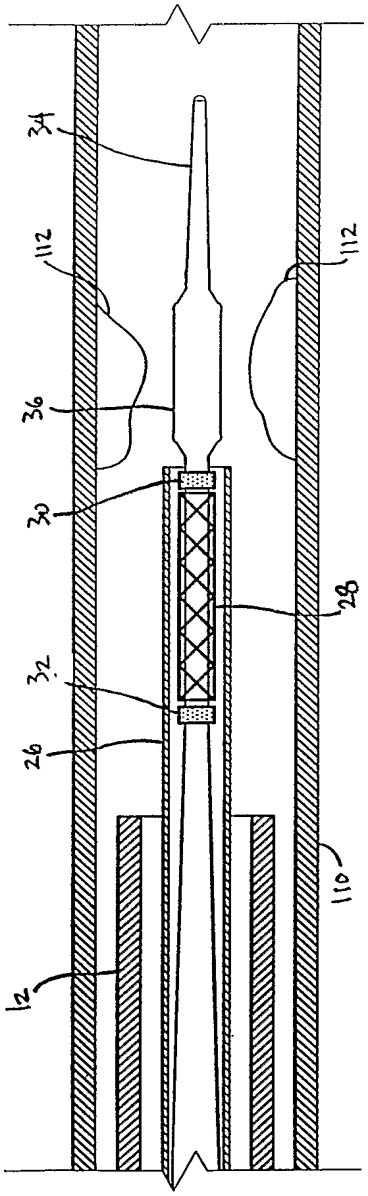

FIG. 7A

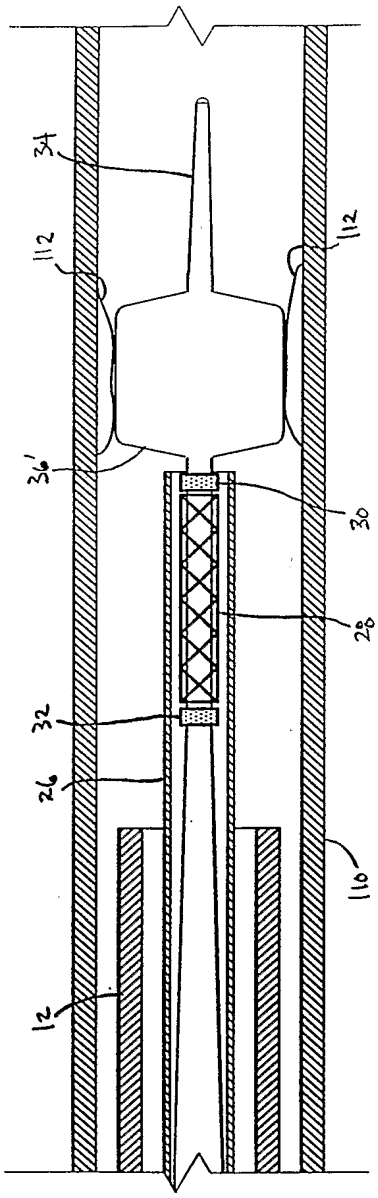

FIG. 7B

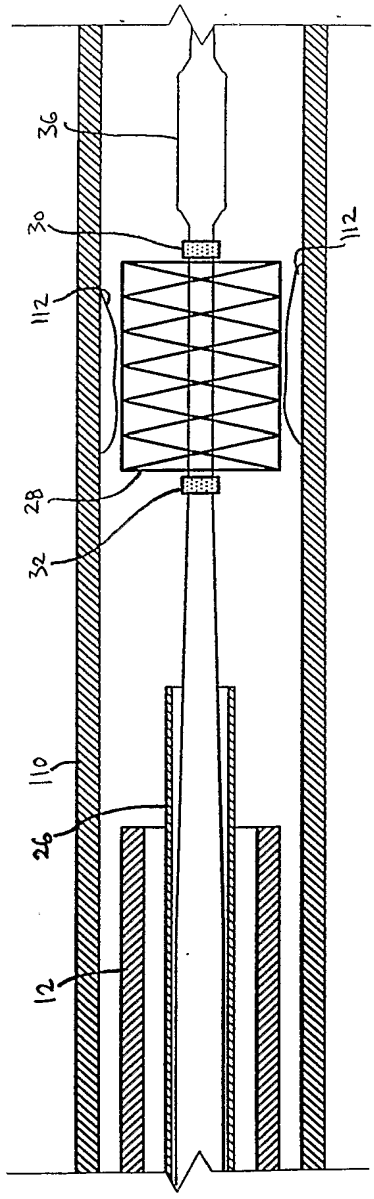

FIG. 7C